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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/762,550	02/09/2001	Akihiro Funakoshi	053466/0299	5276
22428 7590 08/24/2009 FOLEY AND LARDNER LLP SUITE 500 3000 K STREET NW WASHINGTON, DC 20007				
EXAMINER				
SPECTOR, LORRAINE				
ART UNIT		PAPER NUMBER		
1647				
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08/24/2009		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/762,550

Applicant(s)

FUNAKOSHI ET AL.

Examiner

Lorraine Spector

Art Unit

1647

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 July 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14, 16-23, 25 and 26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14, 16-23, 25, 26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/C2)
- Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/9/2008 has been entered.

Claims 14, 16-23, 25 and 26 are pending and under consideration. There have been no amendments to the claims since the response of 8/15/07.

The rejection under 35 USC §103 is withdrawn in view of applicants arguments. New rejections apply.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 14, 16-23, 25 and 26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors considered when determining if the disclosure satisfies the enablement requirement and whether any necessary experimentation is "undue" include, but are not limited to:

1) nature of the invention, 2) state of the prior art, 3) relative skill of those in the art, 4) level of predictability in the art, 5) existence of working examples, 6) breadth of claims, 7) amount of direction or guidance by the inventor, and 8) quantity of experimentation needed to make or use the invention. In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

The nature of the invention is the use of IL-6 inhibitors to treat acute pancreatitis. The exhaustive prosecution has established that both IL-6 and TNF are associated with acute pancreatitis, that IL-6 inhibits TNF-alpha, and TNF-alpha induces IL-6.

The prior art does not recognize IL-6 inhibitors as a treatment for acute pancreatitis, and presents information that does not give a clear picture of whether such treatment would be successful. As stated in the previous rejection under §103, Gross et al. teach that IL-6 concentrations are associated with acute pancreatitis; see page 525. Farkas et al. teach that experimental acute pancreatitis results in increased blood-brain barrier permeability (title), and that such is associated with increased IL-6 levels (page 149, paragraph bridging columns). Accordingly, it would have been obvious to the person of ordinary skill in the art at the time the invention was made to use the compositions taught by Sato et al. or Kishimoto et al. to treat acute pancreatitis, in view of the teachings of Gross et al. and Farkas et al. The person of ordinary skill in the art would have expected success at doing so because the primary references teach the antibodies for the express purpose of inhibiting IL-6 associated responses.

At page 2 of the response filed 7/6/09, applicants argue that a Wikipedia entry on IL-6 shows that IL-6 is both a pro-inflammatory and an anti-inflammatory cytokine. The Examiner notes that applicants have not made *any* of the exhibits of record in an IDS. The first page of the Wikipedia entry is illegible. The paragraph bridging pages 1-2, of which the Examiner can only read the portion on page 2 clearly indicates that IL-6 is a pleiotropic cytokine, having different actions in different situations. Therefore, the argument that it can be either pro-inflammatory or anti-inflammatory, without a more careful examination of *when* it has which activity, is not probative. On the second page, the entry states, under "Functions of IL-6", that "IL-6 is one of the most important mediators of fever and of the acute phase response." This would directly suggest administration of IL-6 inhibitors for acute phase responses, such as acute pancreatitis. The Examiner cannot make the Wikipedia reference of record, as there is in

Exhibit B, a discussion of positive and negative feedback is not directly applicable to the arguments at hand, and merely provides basic definitions of basic terms.

Aderka et al. teaches that IL-6 inhibits TNF-alpha, and, as characterized by applicants, would suggest the administration of IL-6, and not inhibitors of such. Aderka was using an LPS-induced sepsis model, and not a model of acute pancreatitis.

Ulich, as characterized by applicants, teaches that If IL-6 is acting as an anti-inflammatory cytokine as part of an endogenous negative feedback loop, the person of ordinary skill in the art would expect that IL-6 would occur later in inflammation, rather than earlier. Ulich was using a model of intratracheal injection of endotoxin, and not a model of acute pancreatitis.

The Examiner takes no issue with applicants characterization of Norman et al.

Thus, while the Examiner has made a case *for* inhibition of IL-6 in acute pancreatitis (see 103 rejection in previous Office Actions), applicants have made a case *against* such.

Accordingly, there is no consensus in the art.

In this particular case, given the teachings in the art, there is no predictability about *whether* administration of IL-6 would be beneficial to patients having acute pancreatitis, nor *how and when* such should be administered; clearly, looking at the most recent reference cited by applicants in their most recent submission, timing would be critical.

There are *no* working examples in which *any* anti-IL-6 molecule was administered to *any* animal or human either having acute pancreatitis, or an accepted model of such.

The claims do not specify how or when the active agent is to be administered.

Accordingly, the Examiner concludes that it is not predictable that the claimed invention would work *at all*. Nor is there sufficient disclosure to allow the skilled artisan to practice the claimed invention without substantial experimentation. All applicants have presented is the germ of an invention, and an invitation to determine how to practice that invention.

A patent is granted for a completed invention, not the general suggestion of an idea and how that idea might be developed into the claimed invention. In the decision of Genentec, Inc, v. Novo Nordisk, 42 USPQ 2d 100,(CAFC 1997), the court held that:

“[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable” and that “[t]ossing out the mere germ of an idea does not constitute enabling disclosure”. The court further stated that “when there is no disclosure of any specific starting material or of any of the conditions under which a process is to be carried out, undue experimentation is required; there is a failure to meet the enablement requirements that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art”, “[i]t is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement”.

The instant specification is not enabling because one cannot, following the guidance presented therein, practice the suggested method without first making a substantial inventive contribution.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Lorraine M. Spector. Dr. Spector can normally be reached Monday through Friday, 9:00 A.M. to 3:00 P.M. at telephone number 571-272-0893.

If attempts to reach the Examiner by telephone are unsuccessful, please contact the Examiner's supervisor, Dr. Manjunath Rao, at telephone number 571-272-0939.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

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Official papers filed by fax should be directed to **571-273-8300**. Faxed draft or informal communications with the examiner should be directed to **571-273-0893**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Lorraine Spector/
Primary Examiner, Art Unit 1647

Lorraine Spector, Ph.D.
Primary Examiner